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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,987	03/20/2001	Joseph P. Loeffler	016770-004500US	1516

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EXAMINER
WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/812,987	Applicant(s) Loeffler et al
	Examiner Joseph Weiss	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 27, 2003*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above, claim(s) *1-36* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *37-49* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. This application contains claims 1-36 drawn to an invention non-elected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's argument that because he has set forth his intended use for the device, it cannot be restricted out. Applicant is in error, it is irrelevant what applicant intends to use the device for. What matters is what the device can do. The instant device can feed liquids to many devices, not just aerosol generating devices, e.g. syringes for liquid stream deliver, volitalizers/vaporizers for vapor deliver, *etc*. Therefore applicant's arguments are not persuasive and the restriction is made final.

Information Disclosure Statement

2. The information disclosure statement filed 3 Dec 01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 37 & 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramseyer et al. (US 5515842).

In regards to claim 37, Ramseyer discloses the insertion of an ampoule (10) into an aerosolization device having a liquid feed system (1/5), an aerosol generator (3/6/19) and an exit opening (6); opening an ampoule (note interface of element 23 of 4 with 24 of 1 when device is placed in operation figs 2-3 and supporting text) to permit liquid from the ampoule to drain into a liquid receiving region (4) of the feed system; and operating the aerosol generator to eject liquid droplets through the exit opening (note operation of piston 11/13).

In regards to claim 44, Ramseyer discloses vibrating an aperture plate of the aerosol generator to produce liquid droplets (note element 3).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 38-41, 45-46 & 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramseyer.

In regards to claims 38 & 46, Ramseyer substantially discloses the instant application's claimed invention to include a bottom tab that is removable from the ampoule during operation to permit drainage of the ampoule, but does not disclose removal of the bottom tab before insertion of the ampoule into the aerosol device, i.e. a mere reversal/rearrangement of known parts/steps for a known purpose

It is noted that applicant's specification does not set forth this reversal/rearrangement of parts/steps, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 39, Ramseyer discloses the ampoule being held within a receiver unit (1) of the liquid system and where the device is fully capable of having the receiver unit inserted

into the aerosolization device and then coupling of the receiver unit with the liquid receiving region.

In regards to claim 40, Ramseyer's device is fully capable of the method step of removing the receiver unit from the aerosolization device following operation of the aerosol generator and discarding the receiver unit.

In regards to claim 41, Regarding the cleaning step after use, one of ordinary skill in the art would appreciate the necessity of cleaning a medicament delivery device after use to prevent cross contamination between uses to prevent harm to a patient.

In regards to claim 45, Ramseyer discloses a device that is fully capable of the method steps of inserting a receiver unit (1) of a liquid feed system (1/5) into an aerosolization device having an aerosol generator (3/6/19) wherein the receiver unit includes an ampoule (10) containing a liquid, and wherein the receiver unit is inserted until coupled to a liquid receiving region (interface of 23/23) to a liquid receiving region (4) of the feed system that is interfaced with the aerosol generator.

In regards to claim 49, Ramseyer discloses the method of claim 45 further comprising vibrating an aperture plate of the aerosol generator to produce liquid droplets an aperture plate of the aerosol generator to produce liquid droplets (3 & supporting text).

7. Claims 42 & 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramseyer as applied to claims 37 & 45 above, and further in view of Deussen et al. (US 4926915).

In regards to claim 42 & 47, Ramseyer substantially discloses the instant application's claimed invention to include necessary manipulation of the ampoule after insertion to insure proper use, but does not explicitly disclose removal of a top tab from the ampoule to form a vent. However, Deussen disclose such (vent 41, top tab 14). The references are analogous since they are from the same field of endeavor, the dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Deussen and used them with the device of Ramseyer. The suggestion/motivation for doing so would have been to insure optimal flow and emptying of the ampoule by eliminating gas head space resistance and prevention of aerosolization interruption by gas in ampoule head space. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

8. Claims 43 & 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramseyer as applied to claims 37 & 45 above, and further in view of Ljungquist (US 5925019).

In regards to claim 43 & 48, Ramseyer substantially discloses the instant application's claimed invention to include an overflow region adjacent tot eh ampoule (note the space within 1 & between 10), but does not explicitly disclose permitting excess liquid to flow into the overflow

region. However, Ljungquist disclose such (See col. 6 line 10-15). The references are analogous since they are from the same field of endeavor, the dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Ljungquist and used them with the device of Ramseyer. The suggestion/motivation for doing so would have been to prevent the aerosol generator from being overwhelmed with liquid from the feed system to prevent proper aerosol formation. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 37-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 09/812,755. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth a method of aerosolization comprising the steps of inserting an ampoule that contains liquid into an aerosolization device, opening the ampoule to drain liquid from the ampoule to drain it into a liquid receiving region of the device, operating an aerosol generator to eject liquid through an exit opening of the aerosol generator.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 37-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 09/876402. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth a method of aerosolization comprising the steps of inserting an ampoule that contains liquid into an aerosolization device, opening the

ampoule to drain liquid from the ampoule to drain it into a liquid receiving region of the device, operating an aerosol generator to eject liquid through an exit opening of the aerosol generator. .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 37-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 09/876542. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth a method of aerosolization comprising the steps of inserting an ampoule that contains liquid into an aerosolization device, opening the ampoule to drain liquid from the ampoule to drain it into a liquid receiving region of the device, operating an aerosol generator to eject liquid through an exit opening of the aerosol generator.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5970974, 5950619, 5819730, 5582330, 5383906, 5122116, 4934358, 4872553, 4693853, 4101041, 4052986, 3908654, 3325031, 1680616, 550315; PCT WO92/17231

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

JWeiss

February 7, 2003

WEILUN LO
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